PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/03274	International filing date *(day/month/year)* 02.07.2003	Priority date *(day/month/year)* 02.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant OPTINOSE AS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 11 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02.02.2004	17.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Krantz, L Telephone No. +49 89 2399-2523

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/03274

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-33	as originally filed

Claims, Numbers

8-51, 67 (part), 68-85	as originally filed
1-7, 52-66, 67 (part)	received on 26.04.2004 with letter of 26.04.2004

Drawings, Sheets

1/15-15/15	as originally filed

2. With regard to the **language,** all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 26-51,67-85

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 67-81 are so unclear that no meaningful opinion could be formed *(specify)*:

   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 26-51,82-85

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-81 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-25,53-66
	No:	Claims	1,52
Inventive step (IS)	Yes:	Claims	6,25,54,66
	No:	Claims	1-5,7-24,52,53,55-65
Industrial applicability (IA)	Yes:	Claims	1-25,52-66
	No:	Claims	26-51

2. Citations and explanations

see separate sheet

claims 1 , 26 , 52 and 67 are independent .
claim 26 is for a method.

The following documents cited in the International Search report are referred to by means of the following appellation:
D1 : US-A-2 470 297
D2 : WO-A-99-58180

D3 : EP-A-1 180 378
D3 is also cited page 33 as WO-A-00-51672 and is from the same Applicant , Optinose ltd.
D4 : EP-A-779 078

III

Independent claim 67 is unclear and not concise
If a claim defines :
"An automobile FOR receiving and actuating a radio ..."
then specifications of details in the radio (apart from the antenna-plug and the power-supply plug which have to match plugs in the car) such as short-wave and medium-wave ranges or AGC are superfluous and confusing because the claim merely concerns the car , not the radio.
Therefore most of the details of the interface unit in claim 67 are superfluous.

Furthermore since the design of the delivery unit is unknown then the geometry or functions of the drive unit in the actuation unit also becomes unknown.
In the above example it corresponds the following definition: "the automobile comprising a drive unit for actuating the power-supply of the radio"
When it is not known if the radio operates on 6 volt or 12 volt or 20 volt nor how many milliAmps the radio needs then the drive unit also becomes unpsecified.
In D3 fig 2 the actuation unit 20 has a drive unit 26 (exhaled air enters through 26) for actuating delivery unit 32.

III .2

claims 68 - 81 are unclear
These claims define irrelevant details of the interface unit which is not even part of claim 67.

III .3

Claims 26 - 51 have not been searched and are not examined for the same reason namely that the methods of delivering a substance to the airways of a person is a therapy Rule 67.1.iv EPC

III .4

Claims 82 - 85 consist merely of references to the description see the search report.

IV

Lack of unity :
The claims define the following three groups of inventions whereof (at least) two groups are independent inventions:
claims 1 - 25 nasal delivery device as in fig 2 with an actuation unit 23

claims 52 - 66 nasal delivery component as in fig 3 which is similar to the interface unit 21 of claim 1

claims 67 - 81 an actuation unit 23 as in fig 5

PCT-Rule 13 requires that all independent claims should have features IN COMMON which are new and inventive.
These are the essential features of the invention , which features should ALL be present in EACH independent claim see PCT-Guidelines C-III 4.4
Since the entire claim 52 is not new over D1 then the claim cannot possible have any new features in common with independent claims 1 and 67.

A further reason for lack of unity is that the actuation unit of claim 1 may be completely different from the actuation unit in claim 67 which

is the entire subject-matter of claim 67.
Thus the actuation unit of claim 67 has a drive unit which the actuation unit of claim 1 maybe has not.
Furthermore the shape and form of the delivery units in claim 1 and claim 67 which are acted upon by the actuation unit may be entirely different.
For instance two actuation units for actuating two transportation units including seats for passengers may be very different if one transportation unit is a rocket and the second is a car.
Yet the Applicant has paid an additional examination fee.

V

The subject-matter of claim 1 is not new over D2 :
An axle may well be said to include parts A , B and C although the axle is one solid piece.
A , B and C may well be names for portions of the axle having different shapes or being of different materials or even being identical in design but with different functions when in use.

According to the description and fig 3 the interface unit 21 comprises:
1 - a nosepiece unit 27
2 - a nozzle 35
3 - a delivery unit 39
(in fig 3 the arrow from 39 points to gas-channel 37)
4 - a substance supply unit 43 , 47 , 55
See also page 15 line 14 :
"The interface unit 21 further comprises ... nosepiece units 27 ... each comprise a cuff 31 ... and an outlet unit 33 ... Each outlet unit 33 comprises a nozzle 35"
On page 16 line 4 the list of which parts are inside the interface unit 21 is continued:
"The interface unit 21 FURTHER comprises ... delivery units 39 ... each comprise a substance supply unit 43"

Such four parts can all be identified in the disposable , single-use , replaceable interface unit 3 (capsule 3) in D2 fig 8.
This capsule 3 is for single use see six-package in D2 fig 7.

The interface unit 3 in D2 fig 8 comprises:
- a nosepiece unit for fitting in a nostril
  The top of capsule 3
  see D2 page 9 first line "nasal passages"
- a nozzle
  the middle portion of capsule 3 above seal 31
- delivery unit
  the bottom portion of capsule 3 below seal 31 to the bottom
- the delivery unit including a substance supply unit 9 , 17 , 31
  (sealed compartment) for delivering substance 9 to
  the nozzle of the nosepiece

Furthermore in D2 fig 2 there is an actuation unit 15 , 21 , 23 which can actuate the delivery unit 17 , 31 (by piercing the seals 17 and 31 and blowing out powder 9).
Thus the present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claim 1 is not new , Rule 64 PCT.

V .2

Claim 1 lacks novelty over D3 :
In D3 fig 2 the interface unit 30 , 32 , 34 is releasably attached to the mouthpiece 26 see D3 column 11 lines 35 - 40 whereby the interface unit is a replaceable disposable unit.
- nosepiece unit 30
- nozzle 34
- delivery unit 32 including a :
- substance supply unit
  D3 column 12 lines 25 - 30 :
  inside unit 32 fig 2 may consist of a gas source and
  a compartment with powder medicine.
  This compartment is the substance supply unit

- actuation unit 20 , 26
  when the user exhales through mouthpiece 26 and his airflow surmounts the resistor 28 then this airflow is used to activate the supply unit 32 D3 column 12 lines 29 - 47

V .3

The subject-matter of claim 52 is not new over D1 :
The features of claim 52 are seen as follows in D1 :
- nasal delivery component D1 fig 1 and column 2 line 24 :
  "material will pass on through the nose".

comprising a :
- nosepiece-unit each branch 24 or tip 24 D1 fig 6

and including a :
- nozzle 22 (where the branches 24 meet)

- delivery-unit : housing 10 with air channel 32 with ball 34
  the ball hitting the capsule 26 by inhalation whereby
  medicine is shaken out of capsule 26

- substance-supply unit : capsule 26 with powdered medicament , col.3 L.11 .

It may be argued that the
"device of document D1 is re-usable and manifestly not
a disposable single-use device"
In the first line of claim 52 of the invention it is stated as a mere wish that the nasal component is a disposable component , there are no details about the rest of the features in claim 52 which make them specially adapted for being disposed of.
The components of the device in D1 are not made of gold or platin but naturally , to sell the device best possible , of the cheapest functional materials available.
Furthermore as shown above the components in D1 are identical to those of claim 52 whereby the device in D1 is just as disposable.

Actually there is no device in the world which cannot be disposed of after a single use.

V .4

The following dependent claims are considered new and inventive

over the available prior art :
claim 6 : in D2 fig 7 the interface units 3 are in a belt structure but the actuation unit 5 cannot use this belt as guide , the user has to separate the belt.
In D3 fig 8 only the powder doses 94 are in a disc-structure.

claim 25 : delivery of medicine to both nostrils with a time delay inbetween is not seen in the available prior art .
Thus for instance in D4 fig 2 both nose-tubes 28 branches directly from the same cavity 19.

For the same reasons claims 54 and 66 (subclaims of claim 52) are considered inventive.

V .5

The remaining dependent claims are considered obvious in the light of D1 , D2 or D3 :
Only the more complex claims are commented upon below .
For instance :
Claim 4 : the interface units 3 in D2 fig 7 are in a protective packaging (which medical items are not ?)

Claim 7 : in D3 fig 9 there is an substance pump unit (aerosol canister 120) with a piston 122 (valve stem 122) which is moveable in the chamber of the canister. Further to interface unit 120 + 122 + nosepiece nozzle 132 there is an actuation unit 112 + 130 (mouthpiece 112 + lever 130) D3 columns 19 and 20.

Claim 11 : If in D3 fig 9 the trigger valve 116 is defined as the actuation unit in claim 1 of the invention and the rest in D3 fig 9 as an interface unit then the interface unit has a mouthpiece 114 which via valve 116 is fluidly connected to a nosepiece 132.

Claim 14 (when appended to claim 12) : In D3 fig 9 there is a gas

supply unit 112 , 116 (mouthpiece and valve) which supplies gas into the nosepiece 132 (through valve 116 D3 column 21 line 5 "the flow of ... exhaled air")
The substance supply unit 120 , 122 is not actuated until this gas flow has reached a certain level D3 col.21 L.7 - 10 :
"Once this predetermined flow rate has been achieved ... triggering ... valve stem 122"

claim 19 : In D3 fig 2 there is a detection unit 24 for exhalation and the flow is used to power the medicament supply 32
D3 column 5 top : "flow of exhalation ... is used to power a mechanism which disperses" .
This flow measurement 28 may be replaced by pressure sensing D3 column 15 lines 50 - 55 "pressure-triggered valve ... in the mouthpiece"

V .6

Other problems:
Page 16 line 5 it is said that the delivery units 39 are CONNECTED TO the nosepiece units 27 but in fig 3 nr. 39 appears to be INSIDE the conical nosepiece 27.

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

*

CLAIMS

1. A nasal delivery device for delivering substance to a nasal airway of a subject, comprising:
an interface unit, as a replaceable unit, including: at least one nosepiece unit for fitting to a respective nostril of a subject and including a nozzle from which substance is in use delivered; and at least one delivery unit including a substance supply unit for delivering substance to the nozzle of the at least one nosepiece unit; and
an actuation unit for actuating the at least one delivery unit of the interface unit.

2. The delivery device of claim 1, wherein the interface unit comprises a disposable unit.

3. The delivery device of claim 1 or 2, wherein the interface unit comprises a single integral unit.

4. The delivery device of any of claims 1 to 3, wherein the interface unit is packaged in protective packaging.

5. The delivery device of any of claims 1 to 4, comprising:
a plurality of interface units attached to a belt such as to allow for successive attachment of the interface units to the actuation unit.

6. The delivery device of claim 5, wherein the actuation unit is configured successively to provide the interface units thereto through use of the belt as a guide.

7. The delivery device of any of claims 1 to 6, wherein the substance supply unit comprises a substance pump unit for delivering substance, the substance pump unit including a chamber containing substance and a piston member which is movable in the chamber to deliver a flow of substance from the chamber.

52. A nasal delivery component, as a disposable component, comprising at least one nosepiece unit for fitting to a respective nostril of a subject and including a nozzle from which substance is in use delivered, and at least one delivery unit including a substance supply unit for delivering substance to the nozzle of the at least one nosepiece unit.

53. The delivery component of claim 52, wherein the delivery component is an interface unit for attachment to an actuation unit utilized in actuating the at least one delivery unit.

54. The delivery component of claim 53, wherein a plurality of delivery units are attached to a belt such as to allow for successive attachment to the actuation unit.

55. The delivery component of claim 53 or 54, wherein the at least one delivery unit is manually actuatable absent an actuation unit.

56. The delivery component of any of claims 52 to 55, wherein the delivery component is packaged in protective packaging.

57. The delivery component of any of claims 52 to 56, wherein the substance supply unit comprises a substance pump unit for delivering substance, the substance pump unit including a chamber containing substance and a piston member which is movable in the chamber to deliver a flow of substance from the chamber.

58. The delivery component of claim 57, wherein the substance is a liquid.

59. The delivery component of claim 57, wherein the substance is a powder.

60. The delivery component of any of claims 52 to 59, further comprising a mouthpiece unit including a mouthpiece into which the subject in use exhales.

61. The delivery component of claim 60, wherein the mouthpiece is fluidly connected to the at least one nosepiece unit such as to provide an air flow therethrough on exhalation by the subject into the mouthpiece.

62. The delivery component of any of claims 52 to 61, wherein the at least one delivery unit includes a gas supply unit for supplying a gas flow through the at least one nosepiece unit.

63. The delivery component of claim 62, wherein the gas supply unit comprises a gas pump unit for delivering a gas flow, the gas pump unit including a cylinder and a piston member which is movable in the cylinder to deliver a gas flow through the respective nosepiece unit.

64. The delivery component of claim 63, wherein the at least one delivery unit is configured such that the gas supply unit initiates supply of a gas flow prior to the substance supply unit delivering substance.

65. The delivery component of any of claims 52 to 64, comprising first and second nosepiece units for fitting to respective nostrils of the subject, and first and second delivery units, each for delivering substance through a respective one of the first and second nosepiece units.

66. The delivery component of claim 65, where configured such as to be separable between the first and second nosepiece units, and thereby provide two delivery units which are each separably operable.

67. An actuation unit for receiving and actuating an interface unit, as a replaceable unit, to deliver substance to a nasal airway of a subject, the interface unit including at least one nosepiece unit for fitting to a respective nostril of a subject and including a nozzle from which substance is in use delivered, and at least one delivery unit including a substance supply unit for delivering substance to the nozzle of the at least one nosepiece unit, the actuation unit comprising: